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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/521,442 03/07/00 MENON

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EXAMINER

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ART UNIT	PAPER NUMBER
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1615

DATE MAILED:

03/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/521,442	MENON, GOPINATHAN K.	
	Examiner Liliana Di Nola-Baron	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 February 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 07 March 2000 is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____.
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 20) Other: _____

DETAILED ACTION

The examiner acknowledges receipt of Applicant's request for reconsideration, filed on February 20, 2001.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-13 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Schreuder.

The claimed invention refers to a method of preventing, treating or ameliorating an affected area of the skin or hair, comprising topically applying to said area perilla oil.

Schreuder discloses a composition for the treatment of skin disorders, such as cellulitis or striae (See e.g., col. 1, lines 6-14). Schreuder teaches that the paraffinic oils of the composition may be mixed with esters from unsaturated higher natural fatty acids and from higher natural unsaturated aliphatic alcohols, derived from animal or vegetable oils, including perilla seed oil (See e.g., col. 1, lines 26-47). Additionally, Schreuder teaches that the esters are added to the compositions of the invention in an amount of 1-6% by weight (See e.g., col. 1, lines 48-53).

The method of treatment and the composition disclosed by Schreuder meet the limitations of claims 1-13 and 18-20 of the instant application, as they contemplate a method of preventing, treating or ameliorating an affected area of the skin or hair, comprising topically applying to said area perilla oil. Thus, Schreuder anticipates the claimed invention.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1-13 and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Soma et al.

The claimed invention refers to a method of preventing, treating or ameliorating an affected area of the skin or hair, comprising topically applying to said area perilla oil.

Soma et al. provides a composition for topical application, containing as an active ingredient an extract from a plant of the family Labiatae, for enhancing hyaluronic acid productivity (See e.g., col. 1, lines 6-15). Soma et al. teaches that hyaluronic acid plays important roles in the adhesion and protection of cells, formation of dermal tissues, retention of histionic water and maintenance of flexibility, and that a decrease in hyaluronic acid is linked to symptoms of dermal aging, such as lowering of wetness and tenseness and occurrence of wrinkles and flabbiness (See e.g., col. 1, lines 27-54). Soma et al. includes the Perilla genus among the plant extracts from the family of Labiatae, which enhance hyaluronic acid productivity (See e.g., col. 2, lines 5-59) and teaches that the whole herb or the seeds of various Perilla plants may be used in the composition of the invention (See e.g., col. 3, lines 11-18). Soma et al. teaches that the amount of plant extract in the composition is 0.0001 to 20% by weight and that the composition may contain carriers, diluents and auxiliaries, including antioxidants, ultraviolet absorbers or scattering agents, vitamin A and retinol (See e.g., col. 3, line 49 to col. 4, line 42).

The method of treatment and the composition disclosed by Soma et al. meet the limitations of claims 1-13 and 18-20 of the instant application, as they contemplate a method of preventing,

treating or ameliorating an affected area of the skin or hair, comprising topically applying to said area perilla oil. Thus, Soma et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soma et al., as applied to claims 1-13 and 18-20 above, and further in view of Snider.

The claimed invention refers to a method of preventing, treating or ameliorating an affected area of the skin or hair, comprising topically applying to said area perilla oil and to a method of treating skin affected by acne, comprising preparing a topical composition comprising perilla oil and fish oil.

The teachings of Soma et al. have been summarized above (See 35 U.S.C. 102(e) rejection of claims 1-13 and 18-20). Soma et al. does not include fish oil in the composition and treatment of the invention.

Snider discloses reactive polymers for the treatment of skin disorders (See e.g., col. 1, lines 6-10). Snider teaches that the product of the invention is effective in treating different kinds of eczema or dermatitis of allergic-toxic origin, or funginic, bacteric or chemical origin (See e.g., col. 3, lines 34-39). Snider explains that the component A of the invention can be obtained from natural oil, including fish and perilla oil (See e.g., col. 3, line 65 to col. 4, line 14).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition and method of treatment disclosed by Soma et al., by combining perilla and fish oil in the composition of the invention, as taught by Snider. One of ordinary skill in the art would have been motivated to make such a modification to increase the efficacy of the treatment. Because of the teachings of Soma et al., that plant extracts may be mixed with auxiliaries, one of ordinary skill in the art would have a reasonable expectation that the method of treatment claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

6. Applicant's arguments filed on February 20, 2001 have been fully considered but they are not persuasive.
7. In response to Applicant's argument, that the prior art (Schreuder) discloses esters derived from perilla seed oil, it is noted that the method claimed in the instant application reads on a PPAR stabilizer, such as perilla oil and perilla seed oil. The terms "perilla oil" and "perilla seed oil" are within the scope of the esters of perilla seed oil disclosed in the prior art. Said terms fail to distinguish the claimed invention over the prior art.
8. In response to Applicant's argument, that the prior art (Schreuder) does not specify oily skin conditions and skin break out, it is noted that the term cellulite is defined as accumulation of subcutaneous fat and the term stria is defined as a stripe or line in the skin (See Merriam Webster's Collegiate Dictionary).

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9. In response to Applicant's argument, that the prior art (Soma et al.) discloses perilla extracts in aqueous solvent systems, it is noted that the prior art contemplates preparation of the extracts using organic solvents (See e.g., col. 3, lines 39-48). Furthermore, the terms "perilla oil" and "perilla seed oil" in the claimed invention are within the scope of the whole herb and seed of *Perilla frutescens* disclosed in the prior art and fail to distinguish the claimed invention over the prior art.

10. In response to Applicant's argument, that the prior art (Soma et al.) does not disclose the 0.01-10% concentration range of PPAR stabilizer claimed in the instant application, it is noted that Soma et al. teaches that the amount of plant extract in the composition is 0.0001 to 20% by weight. Even if the extraction in the prior art yields 20% of perilla plant, this would still yield a 5% final concentration of perilla extract, which is in the claimed range of Applicant's invention. The burden is shifted to applicant to establish a distinguishable concentration range over the prior art.

11. In response to Applicant's argument, that the prior art (Soma et al.) does not disclose the effect of hyaluronic acid on PPAR receptors, it is noted that the claimed invention refers to a method of preventing, treating or ameliorating an affected area of the skin or hair. No biochemical mechanism is claimed in the instant application. Further, Soma et al. teaches that hyaluronic acid plays important roles in the adhesion and protection of cells, formation of dermal tissues, retention of histionic water and maintenance of flexibility, and that a decrease in hyaluronic acid is linked to symptoms of dermal aging, such as lowering of wetness and tenseness and occurrence of wrinkles and flabbiness. Wrinkles and flabbiness are associated with

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skin conditions, such as cellulite, blemishes and skin break out, whereas oily skin, scalp and hair conditions are related to formation of dermal tissue.

12. In response to Applicant's argument, that the prior art (Snider) discloses prereacted natural oils, it is noted that the terms "perilla oil" and "perilla seed oil" in the claimed invention are within the scope of the perilla and fish oil disclosed in the prior art. Said terms fail to distinguish the claimed invention over the prior art.

13. In response to Applicant's argument, that the combined prior art does not disclose acid proportion, the burden is shifted to Applicant to establish the criticality of said proportion.

Conclusion

14. Claims 1-20 stand rejected.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

March 1, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600